K113042

Special 510 (k) Summary:

REVOIS® Implant System

MAR 8 2013

1. SUBMISSION INFORMATION

Name and Address of the Sponsor:	Riemser Arzneimittel AG An der Wiek 7 17493 Greifswald-Insel Riems Germany
Date created	March 5, 2013
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Registered U. S. Agent:	James M. Clinton 5105 Fairoaks Rd. Durham, NC 27712, USA Phone: 919 – 247-0479, fax: 919 – 287-2551 E – Mail: clintonjm@earthlink.net

2. DEVICE IDENTIFICATION

Proprietary Name:	*REVOIS*® Implant System
Common Name:	Dental implant system
Classification Name:	Endosseous Dental Implant
Classification:	Class II, Special Controls
Classification regulation Number:	21CFR 872.3640
Product Code:	DZE, Endosseous implant

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3. PREDICATE DEVICE

REVOIS® Implant System: K063106

4. DESCRIPTION OF THE DEVICE

The *REVOIS*® Implant System is a self-contained, modular dental implant system for placement into the jaw bone (upper or lower jaw bone) to support prosthetic devices for dental restoration. The system is designed for one-stage or two-stage surgical procedures.

The *REVOIS*® Implant System is composed of titanium, screw type implant, pre-assembled with a multifunctional precision abutment and a transfer tool that snaps onto the abutment (Snap-on-tool). The implant is also available with a transfer tool only. A cover screw is contained in the top of the snap-on or transfer tool.

The system offers implants in various diameters and lengths (3.8; 4.3; 5.0 mm diameter; 9; 11; 13; 15 mm lengths). The *REVOIS*® Implant System is provided with a number of corresponding tools and surgical instruments, as well as a variety of prosthetic components which are definitely 510(K)-exempt or still cleared by the submission K063106. For ease of identification the implants and corresponding tools are color coded according to diameter.

The main components of the implant system are made of Grade IV or Grade V Titanium. The used materials comply with the ASTM standards ASTM F067, ASTM F0136-2a, and ASTM F2026.

The implant surface is blasted with aluminium oxide and then acid-etched for micro-roughness. Blasting and acid –etching contributes to the implant surface characteristics. Furthermore grooves increase resistance to shear forces in difficult clinical cases.

The *REVOIS*® titanium implant (pre-assembled with the multifunctional precision abutment and snap-on-tool or with the transfer tool only) is supplied in double sterile packages (sterile inner plastic vial in a sterile glass vial, which is sealed in a blister) and is for single use only.

Tools and other re-usable instruments must be sterilized prior to use.

5. STATEMENT OF INTENDED USE

The *REVOIS*® Implant System is an implant system recommended for:

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Surgical placement in the edentulous or partially edentulous jaw bone (upper or lower jaw bone) to create support for prosthetic devices such as single artificial teeth, fixed or removable bridges or dentures.

The titanium implant can be applied either in a one-stage surgical procedure with immediate loading when good primary stability is achieved and with appropriate occlusal loading, or in a two-stage surgical procedure (after osseointegration of the implant).

6. STATEMENT OF TECHNOLOGICAL COMPARISON, BASIS FOR SUBSTANTIAL EQUIVALENCE

The *REVOIS*® Implant System by Riemser is identical to the *REVOIS*® Implant System by cursan that was cleared by K063106. The ownership of the K063106 device was transferred from CURASAN AG to Riemser AG and FDA was notified by a letter to file. The Riemser device like the curasan device provides the same state-of-the art implant technology and options. The design and pre-assembled version of implant, abutment (which fits for all implants and implant diameters) and snap-on/transfer tool offer easy handling for the dentist/surgeon by reducing the number of components needed for successful placement of the implant, while ensuring precision and stability.

The stability of the implant body of the *REVOIS*® implant system thread was tested in non-clinical performance testing as fatigue testing according to ISO 14801 and Bench testing with Animal Model.

The essential similarity conclusion regarding the comparability of *REVOIS*® and *REVOIS*® (CURASAN, K063106)) are displayed in the following:

Both implant systems share similar indications for use. Both systems consist of screw form implants with internal hex connection consisting of titanium of different grades which is an inert, very durable material well known and used in implant surgery. They feature special threads and surfaces intended to support the primary stability of the implant and to ease the insertion, tissue adhesion and osseointegration of the implant into the bone. Both the curasan AG and Reimser AG systems provide implants in various diameters, lengths and color codes to accommodate different clinical situations as well as the matching tools, surgical instruments and accessories. The implants and pre-mounted components where applicable (*REVOIS*®, *REVOIS*® (CURASAN, K063106)), are supplied gamma sterilized in double sterile packaging. Differences between the Riemser *REVOIS*® and the curasan predicate device exist in the implant surface treatment: aluminium oxide blasted / acid etched (Riemser *REVOIS*®) and zirconium blasted / acid-etched (*REVOIS*® (CURASAN, K063106)). Each system has a triple layer of sterility protection: PETG vial in glass vial, sealed in a blister at *REVOIS*®; the *REVOIS*® (CURASAN) comes with PET vial instead of PETG, while the blister and glass vial remain the same.

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In summary, both systems are comparable in their main and most important characteristics. The differences between the systems represent minor updates as described and do not affect the device safety or effectiveness. The Riemser *REVOIS®* and the *REVOIS®* (CURASAN) implant systems are therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Riemser Arzneimittel AG
C/O Mr. James M. Clinton
Principal Consultant
Quality & Regulatory Consulting, Limited Liability Company
5105 Fairoaks Road
DURHAM NC 27712

Re: K113042
Trade/Device Name: REVOIS® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 3, 2013
Received: February 13, 2013

Dear Mr. Clinton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113042

Device Name: REVOIS® Implant System

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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